outcome in MM patients. Between January 2003 and September 2004, 13 MM patients received GM-CSF and IFN-α therapy following ASCT. IFN-α was started within 120 days after ASCT at a dose of 1 million units and increased as tolerated to 4 million units subcutaneously 3 × per week. GM-CSF was started at 125 μg/m^{2}day subcutaneously on the same days with IFN-α. The combination therapy continued for 1 year, after which GM-CSF was stopped. Ten patients receiving this combination therapy (median age, 61 years) were evaluable for analysis. Disease status at the time of enrollment was complete remission in 1 patient, partial remission in 4 patients, and very good partial remission in 5 patients. Six patients had stage III and 4 had stage II, with only 1 in renal failure. Median follow-up from last ASCT was 16 months. Median duration of combination therapy was 7.5 months (range, 1–12 months). The median tolerated dose of IFN-α was 4 million units, although 2 patients had a permanent dose reduction to 2 or 3 million units due to flu-like symptoms. None of the patients dropped from the trial secondary to myelosuppression. Three patients dropped out due to persistent flu-like symptoms or elevated liver function tests secondary to IFN-α, 2 patients dropped out due to disease progression, and 1 patient had a GM-CSF dose reduction due to leukocytosis. Median PLT count and ANC at 3 months were 136,000/μL and 3800/μL, respectively. One patient required Procrit therapy. All patients received GM-CSF and IFN-α therapy for a minimum of 34 days. Two patients improved to CR from PR and VGPR, 2 patients progressed, 5 patients remained stable, and 1 patient was lost to follow-up. Using the method of Kaplan and Meier, median PFS and OS for the whole group have not been reached. In a previous analysis of 25 similar patients who received a median of 8 months of IFN-α–only maintenance therapy (median tolerated dose of 3 million units), 10 patients had to discontinue therapy due to myelosuppression. In conclusion, the addition of GM-CSF to IFN-α is well tolerated and is very effective in preventing IFN-induced myelosuppression. It is too early to tell whether a survival benefit will be realized.

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A PHASE II STUDY OF XCELLERATED T CELLS™ IN PATIENTS WITH RELAPSED OR REFRACTORY INDOLENT NON-HODGKIN'S LYMPHOMA (NHL)

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Background: T cells can be activated and expanded ex vivo using the Xcellerate™ process, in which peripheral blood mononuclear cells (PBMCs) are incubated with anti-CD3 and anti-CD28 antibody–coated magnetic beads (Xcyte™ Dynabeads®). In an ongoing trial of Xcellerated t cells in subjects with chronic lymphocytic leukemia, marked and sustained reductions in lymphadenopathy and splenomegaly were observed. This study is designed to determine whether similar effects can be observed in subjects with indolent NHL. **Methods:** Subjects must have relapsed or refractory indolent NHL. PBMCs are collected by leukapheresis for the Xcellerate™ process, and subjects subsequently receive 2 infusions of 20–60 × 10^9 Xcellerated t cells separated by 6–8 weeks. Approximately 40 subjects will be treated. **Results:** Twenty subjects have been enrolled. The median number of prior treatment regimens was 3 (range, 1–4). Histological subtypes are small lymphocytic (n = 9), follicular (n = 5), mantle cell (n = 4), and marginal zone (n = 2). Xcellerated t cells have been manufactured in 15 subjects to date, and 13 subjects have been treated. No related serious adverse events have been reported to date. Follow-up is available in 8 subjects through week 6. In these subjects, the median number of cells infused was 39 × 10^9 (range, 33–39 × 10^9), of which 98.9 ± 0.2% were T cells (mean ± SD). T-cell counts increased from 728 ± 56/mm^3 before infusion to 1251 ± 953/mm^3 on day 28 (mean ± SD). All 3 SLL subjects had marked reductions in peripheral lymphadenopathy on physical examination, and 2 of these patients also showed decreases on computed tomography scan. However, the patients did not meet radiographic criteria for response; 2 of them had bulky abdominal lymphadenopathy. A bone marrow biopsy specimen obtained in 1 of the SLL subjects revealed a decrease in leukemic involvement from 70% to 40% of cellularity. In 2 subjects with follicular lymphoma, 1 had stable disease radiographically and 1 had disease progression. Three subjects with mantle cell lymphoma had progressive disease. **Conclusions:** Xcellerated t cells can be manufactured in subjects with indolent NHL. Treatment leads to significant increases in T-cell counts. Preliminary data suggest a reduction in peripheral lymphadenopathy and bone marrow involvement in SLL subjects. Data on additional subjects will be presented.

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A PHASE I/II STUDY OF XCELLERATED T CELLS™ AFTER AUTOLOGOUS PERIPHERAL BLOOD STEM CELL TRANSPLANTATION IN PATIENTS WITH MULTIPLE MYELOMA

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Background: Previous studies have demonstrated a correlation between survival and lymphocyte recovery following autologous transplantation in subjects with multiple myeloma and other malignancies. We initiated a trial in the transplantation setting to evaluate the activity of T cells activated and expanded ex vivo with the Xcellerate™ process, which uses anti-CD3 and anti-CD28 antibody–coated magnetic beads (Xcyte™ Dynabeads®). **Methods:** After induction therapy, patients underwent leukapheresis to collect peripheral blood mononuclear cells for the Xcellerate™ process. Patients then underwent stem cell mobilization and collection, followed by high-dose melphalan (200 mg/m^2). Three days after peripheral blood stem cell infusion, subjects received 50–100 × 10^9 Xcellerated T cells. **Results:** A total of 36 subjects were treated. The median last follow-up visit is 360 days posttransplantation (range, 180–630 days). A WaveBioreactor-based Xcellerate III™ process, which was instituted in the last 18 subjects, resulted in a 249- ± 90-fold (mean ± SD) T-cell expansion. An average of 93.6 ± 0.8 × 10^9 cells was infused, of which 97.6 ± 4.0% were T cells. There were no grade 3 or 4 acute infusional toxicities. Median days of neutropenia and thrombocytopenia were 5 (range, 3–43 days) and 4.5 (range, 0–128 days), respectively. Median days of hospitalization were 16 (range, 10–70 days). Lymphocyte recovery was rapid, with counts reaching > 500/mm^3 generally within 1–2 days after T-cell infusion. Historically, lymphocyte recovery to > 500/mm^3 usually does not occur for 3 or more weeks posttransplantation. The rapid lymphocyte recovery included both CD4+ and CD8+ T cells. The mean (± SEM) CD4+ T-cell count at 90 days posttransplantation was 1210 ± 80/mm^3, which is significantly higher than that for historical controls receiving the same treatment regimen without Xcellerated T cells (198 ± 72/mm^3). In 35 evaluable patients, preliminary results demonstrated 9% CRs, 51% VGPRs, 29% PRs, and 11% with PD, using the M-protein at diagnosis as a reference. **Conclusions:** In multiple myeloma subjects, administration of Xcellerated T cells after high-dose chemotherapy and autologous stem cell transplantation leads to rapid lymphocyte recovery. Most subjects achieve clinical responses in the autologous transplantation setting.

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HIGH-DOSE MELPHALAN (HDM) WITHOUT HEMATOPOIETIC PROGENITOR CELL (HPC) SUPPORT FOR TREATMENT OF PLASMA CELL LEUKEMIA

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Primary plasma cell leukemia (PPCL) is a rare subtype of multiple myeloma that follows a rapid clinical course and responds